

## **REMARKS**

Claims 1-6 and 8-23 are pending. Applicant has amended claims 1-6, 17, and 20-23 to recite the use of CD23 (FcεRII) alone. Claim 15 has been amended to convert this claim into independent form. None of these amendments introduce new matter.

In the interests of expediting prosecution, Applicant discusses claims 1-6, 8-14, and 16-23 in light of the two obviousness rejections that were before the Board during appeal. Applicant notes that the Office has concluded that claim 15 is allowable. See Examiner's Answer at page 2.

### **Combination of Johansen, Johnson, and Frank 2**

The Office continues to assert that Johansen (U.S. Pat. 6,087,188) teaches a method of detecting an antibody using a ligand bound to biotin; an antibody to the antibody to be detected; a chemiluminescent acridinium compound bound to avidin; and a method for quantifying specific antibodies. Office Action dated April 6, 2005, at page 3. The Office acknowledges that Johansen does not teach using an IgE receptor to detect or quantify IgE. *Id.* at page 5. Regarding Johnson (U.S. Pat. 6,034,066), the Office alleges that this reference teaches the role of CD23 in regulating the immune response, such as IgE responses. *Id.* The Office believes that Frank 2 (U.S. Pat. 6,060,326) teaches a method for detecting IgE antibodies using a human Fc epsilon receptor. *Id.* The Office combines these references, suggesting that it would have been obvious to one of ordinary skill in the art to use the IgE receptors of Johnson and Frank 2 to measure IgE according to the method of Johansen. *Id.* at pages 5 and 6.

The combination of Johansen, Johnson, and Frank 2 does not render the methods of claims 1-6, 8-14, and 16-23 obvious. Independent claims 1-6, 17, and 20-

23 recite the use of CD23 alone. As the specification teaches, CD23 is the *low* affinity IgE receptor. See specification at page 4, line 16. Neither Johansen nor Frank 2 teach the use of the low affinity receptor, CD23, in a method of detecting and/or quantifying an IgE antibody. Rather, Johansen uses anti-IgE antibodies while Frank 2 uses the high affinity canine FcεR. Moreover, as Applicant has explained, Johnson simply discusses the functions of CD23 in the immune system. This reference does not suggest the use of CD23 in any method for detecting or quantifying IgE, let alone a method that does so while mimicking the *in vivo* interaction of IgE with its target antigen. More importantly, if one were to rely on Frank 2 for a motivation to combine Johansen and Johnson, Frank 2 clearly teaches away from the invention of claims 1-6, 8-14, and 16-23.

At column 1, lines 36-41, Frank 2 teaches that a “canine FcεR molecule provides an advantage over, for example anti-IgE antibodies, to detect IgE because a canine FcεR molecule can bind to a canine IgE with more specificity . . . and more sensitivity (i.e., affinity) than anti-IgE binding antibodies.” Given this teaching, that an advantage of using a receptor lies in its increased affinity over an anti-IgE antibody, one of ordinary skill in the art would not be motivated to use the low affinity receptor (CD23) alone. In contrast, a skilled artisan who wanted to detect all IgE in a sample would want to use a reagent with higher affinity for IgE. Thus, the combination of Johansen, Johnson, and Frank 2 does not render claims 1-6, 8-14, and 16-23 obvious.

Combination of Johansen, Frank 2, and Arnold

The Office uses Johansen and Frank 2 as discussed above. The Office refers to Arnold (U.S. Patent 6,004,745) for an alleged teaching of using two separation steps in a detection assay. According to the Office, it would have been obvious to one of

ordinary skilled in the art to add the label molecule after a first separation step and then separating the non-complexed labels as discussed in Arnold using the reagents in the method of Johansen as modified by Frank 2. Office Action dated April 6, 2005, at pages 6 and 7.

None of the three references, Johansen, Frank 2, or Arnold, teach the use of CD23 in an assay to detect and/or quantify IgE. And, *arguendo*, even if Johansen or Arnold taught the use of CD23, which they don't, the teaching of Frank 2 as discussed above guides the skilled artisan away from the claimed invention. Thus, the combination of Johansen, Frank 2, and Arnold do not render the pending claims obvious.

Conclusions

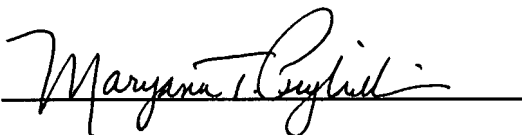
In view of the foregoing amendments and remarks, Applicant respectfully requests consideration this application and the timely allowance of pending claims 1-6 and 8-23.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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